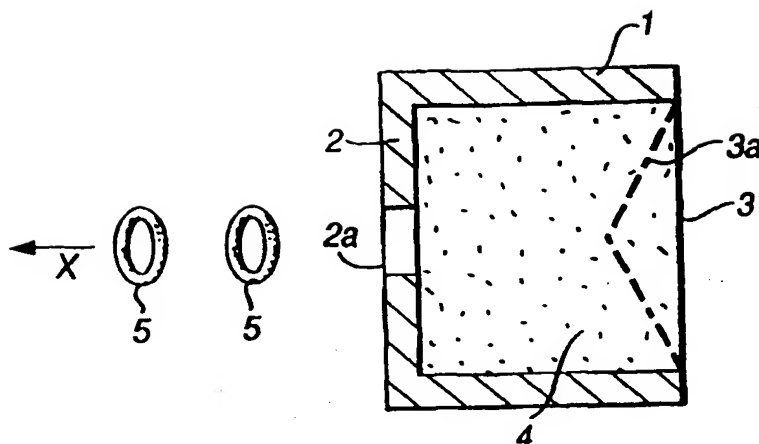


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(54) Title: INHALATION DEVICE**(57) Abstract**

An inhalation device for and method of providing medicament for inhalation, the inhalation device including a vortex generator for generating a vortex entraining particles of medicament in a gas for inhalation by a user.



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INHALATION DEVICE

The present invention relates to an inhalation device for and a method of providing medicament for inhalation.

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Inhalable pulmonary medicaments for combating asthma have been in use since 1935. At first, use was made of an aqueous solution of a medicament which was inhaled in droplet form. Later, medicaments were mixed with gases which expand and are delivered in droplet form. Later again, inhalation devices were developed, by means of which
10 medicaments could be inhaled in powder form.

It is common to all inhalation systems that the medicament is introduced as an uncontrolled cloud, most of which is deposited in the oral cavity and throat, with only a small part reaching the destination in the lungs. It would therefore be of very great advantage if the
15 medicament could be administered into the oral cavity as a controlled narrow jet or spot dosed to a small area, by means of which the dosing can be aimed directly towards the location in the neck region where the windpipe begins. In this way, scattering and the undesirable deposition of medicament in the throat and mouth are greatly reduced.

20 It is an aim of the present invention at least partially to overcome the above-mentioned problems of the prior art.

Accordingly, the present invention provides an inhalation device for providing medicament for inhalation, including a vortex generator for generating a vortex entraining particles of
25 medicament in a gas for inhalation by a user

The present invention also provides a method of providing medicament for inhalation, comprising the step of generating a vortex entraining particles of medicament in a gas for inhalation by a user.

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CONFIRMATION COPY

The principle underlying the present invention is the use of the physical concept of a vortex. Such vortices include the smoke rings which are generated, for example, from the exhausts of diesel engines in certain fishing boats. In more detailed studies of the nature of these smoke rings, it has been observed that the particles which are entrained by the air
5 movements associated with the smoke rings are transported in an unimpeded manner and in the same concentration. Formation of these vortices can take place in many ways, and, if the air in a vortex ring entrains particles of medicament, these particles will be carried along unimpeded and be concentrated in the annular air flow formed.

10 Preferred embodiments of the present invention will now be described hereinbelow by way of example only with reference to the accompanying drawings, in which:

Figure 1 illustrates a component part of the vortex generator of an inhaler in accordance with a first embodiment of the present invention;

15

Figure 2 illustrates in enlarged scale a vortex ring generated by the inhaler of the first embodiment of the present invention;

Figure 3 illustrates a sectional view of the inhaler of the first embodiment of the present
20 invention;

Figure 4 illustrates a sectional view along section I-I in Figure 3 of the inhaler of the first embodiment of the present invention;

25 Figure 5 illustrates a sectional view of an inhaler in accordance with a second embodiment of the present invention;

Figure 6 illustrates modified plungers and a modified tube for the inhaler of the second embodiment of the present invention;

30

Figure 7 illustrates a sectional view of an inhaler in accordance with a third embodiment of the present invention, illustrated in the unloaded position;

Figure 8 illustrates a sectional view of the inhaler of the third embodiment of the present invention in the loaded position; and

Figure 9 illustrates a plan view of the cover of the inhaler of the third embodiment of the present invention.

10 An example of a vortex generator for generating a concentrated moving ring of air/medicament of, for example, roughly 5 mm in diameter is shown in Figure 1. A round tube 1 (for example 30 mm in diameter) has a front plate 2 in which there is a hole 2a (for example 3 to 4 mm in diameter). A flexible rubber diaphragm 3 is fixed as an end plate in the opposite end of the tube 1. This rubber diaphragm 3 can be pushed into the tube 1, as
15 shown by 3a. The tube 1 contains suspended particles of medicament 4.

In the event of rapidly acting on the rubber diaphragm 3, so that it is pushed into the forward position 3a, a vortex ring 5 will be formed, which leaves the hole 2 and moves in the direction of arrow X. A moving vortex ring 5 travelling through the air will be formed
20 each time the rubber diaphragm 3 is acted upon. The vortex ring 5 rotates about both its longitudinal axis and in the direction of rotation as shown in Figure 2. In popular language, it may be said that the vortex ring 5 rolls through the air which acts as a form of roadway.

25 Figures 3 and 4 illustrate an inhaler in accordance with a first embodiment of the present invention.

An external cylindrical shell is shown by 6. The shell 6 includes a mouthpiece with holes in the periphery shown by 7. A tube 8 contains particles of medicament 4, and an exit hole
30 for the vortex rings 5 entraining medicament is shown by 9. Between the shell 6 and the

tube 8, there are a plurality of bearing rollers 10, and inside the tube 8 a plurality of fins 11. An electric mini-motor 12 drives the tube 8 round and actuates a conical striker wheel 14. Batteries for operating the motor 14 are shown by 15. The tube 8 has a rear wall made of a flexible material, for example of rubber, shown by 16.

5

When the motor 12 is started, the tube 8 will rotate. In this connection, the particles of medicament 4 will be whirled round by the fins 11 so that the air in the tube 8 contains an essentially homogeneous air/medicament mixture. A spring wind-up mechanism is built into the conical striker wheel 14 so that the wheel 14 is released only after several
10 revolutions of the motor 12, and this release takes place suddenly and rapidly so that a brief thrust against the rubber diaphragm 16 is brought about. When this thrust is applied to the diaphragm 16, moving vortex rings entraining medicament as shown by 17 will be formed.

15 On inhalation, air will be drawn by the user through the holes 7 in the mouthpiece, and the vortex rings 17 will then accompany this air flow which can be quite gentle and weak.

From a purely practical point of view, it is important that the air/medicament mixture is uniform at the beginning of each inhalation treatment so as to achieve uniform dosing.
20 This can be achieved by, for example, a small plastic bag containing the medicament being inserted into the tube 8 before inhalation. In this embodiment the bag is configured such that the vanes 11 on the walls of the tube 8 extend thereinto so that the medicament, on rotation of the latter, is effectively mixed with the air. The bag, with any medicament residue, is removed after use, that is, after inhalation.

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It will be understood that the above-described method embodies only one method for forming vortex rings entraining medicament. Likewise, it will be clear that gases other than air can be used, for example, carbon dioxide. Air, however, is the simplest to use.

Figure 5 illustrates an inhaler in accordance with a second embodiment of the present invention.

In this embodiment, 18 is a tube and 19 is a plunger connected to a connecting rod 20 and a piezoelectric crystal 21. The cavity of the tube 18 contains medicament in the form of powder or vapour/droplets 22 suspended therein. When the crystal 21 vibrates, either directly or via a gear/lever system so as to achieve greater striking capacity, the plunger 19 in the tube 18 will be advanced in a sudden thrust with very great acceleration, with the air/medicament mixture 22 then being expelled as vortex rings 23 and moving forwards through the air.

Figure 6 illustrates modified plungers 24a, 24b, with conical and part-spherical tips, it being possible to use a number of different constructions to achieve the desired vortex ring. Figure 6 also illustrates a modified tube 25, the tube 25 being provided with a rough internal surface 26 so as to achieve an improved efficiency in vortex formation. Generally, however, it is a sharp aperture opening that is used in vortex formation. It will also be understood that a piezoelectric crystal, as the vibration generator, can be used in all embodiments, namely aperture opening or tube outlet, diaphragm or plunger.

Figures 7 to 9 illustrate an inhaler in accordance with a third embodiment of the present invention.

In Figure 7, 27 represents a round pulse-pressure container, and 28 represents a plunger which is connected to a push-rod 29. The pressure container 27 is provided with a hinged cover 30 on which a plurality of, in this embodiment eight, fork pins 31 are mounted, around which a rubber or plastic balloon 32 containing medicament in the form of a powder can be fixed. By a screwing movement of the vanes 33, the fork pins 31 are made to rotate outwardly towards the periphery of the cover 30 by means known in the art from, for example, variable aperture openings, and guided in a rotary path 35 as shown in Figure 9. The cover 30 has a central hole 36 through which vortex rings 34 are in use generated.

In order to introduce medicament into the inhaler, the cover 30 is opened and the fork pins 31 are, by means of rotation of the vanes 33, made to move inwardly towards the centre of the cover 30 to the position 31a as shown in Figure 9. The balloon 32 has in the bottom thereof a separate pocket containing medicament in the form of a powder, and the balloon 32 is fitted on the fork pins 31 as shown in Figure 7. The cover 30 is closed in on the container 27 and, by means of the vanes 33, the fork pins 31 are moved to the outer position 31b as shown in Figure 8. Figure 9 shows the fork pins 31 in the outer position 31b, as they have been moved along the grooves 35 in the cover 30. In this connection, the balloon 32 will be dilated and the pocket containing medicament in the bottom of the balloon 32 will break so that the medicament will escape therefrom. When the container 27 is shaken, the particles of medicament will float around in the balloon 32. When the plunger 28 is actuated so as to thrust several times in a pulse-like manner, typically by an electronically-controlled piezoelectric crystal, motor hammer or solenoid hammer against the balloon 32, vortex rings 34 will be generated which exit the hole 36, which vortex rings 34 entrain particles containing medicament and move forwards. After use, the cover 30 of the container 27 is opened, the fork pins 31 are screwed back to inner position 31a by rotation of the vanes 33, and the balloon 32 and any medicament residue is removed.

By changing the thrust velocity/acceleration and thrust length of the actuating plunger, for example as controlled by a microprocessor, the velocity and the compression of the air mass which forms the vortex ring can likewise be changed, by means of which the velocity, diameter and ring thickness of the vortex rings of air and medicament are also changed. By changing the aperture opening, through which the vortex rings are generated, the diameter and velocity of the latter are likewise changed. Moving vortex rings of different diameter and with different velocity are obtained, or vortex rings in which only one parameter is changed. It is also possible to cause the vortex rings to collide and in this way change their behaviour, in terms of both diameter and velocity, as the vortex rings can be made to move in and out of one another. By a combination of one or more of these modifications, it is possible to control the movement and behaviour of the vortex rings in

the oral cavity, as the diameter as well as the volume, that is to say the thickness of the vortex rings, and both the relative and absolute velocity of the vortex rings are changed.

Transport of particles and liquid droplets by means of vortices can be used in many other applications where such transport is of interest. For example, lacquer powder can be transported in this manner in lacquering, or vortex transport can be used for volatile paints. Another example is field spraying, the insecticide or herbicide sprayed reaching the surface of the field without great quantities evaporating as they do now.

CLAIMS

1. Dosing principle and method of delivery of (pulmonary) medicament for inhalation, characterized in that the medicament in the form of powder or in the form of liquid droplets or liquid vapour is delivered as part of an air/gas vortex, in particular an annular vortex, or so-called vortex ring, which propagates at substantially right angles to the flat area of the ring.
2. The dosing principle and method of claim 1, wherein the vortex rotates about its longitudinal axis at the same time as moving.
3. The dosing principle and method according to claim 1 or 2, wherein medicament vapour constitutes 100% of the gas which forms the vortex.
4. The dosing principle and method according to any of claims 1 to 3, wherein the medicament is concentrated in the vortices formed, delivered without loss and can be made, within narrow limits, to strike accurately the regions which result in the least medicament loss, that is to say, the fewest deposits in the throat and oral cavity on inhalation.
5. The dosing principle and method according to any of claims 1 to 4, wherein the medicament transport is independent of the inhalation capacity of the patient because the transport path and transport velocity of the vortex ring are determined by the vortex generating device.
6. The dosing principle and method according to any of claims 1 to 5, wherein the medicament is contained in a rubber or plastic bag which is acted on by a pulsed thrust, and the medicament, if appropriate mixed with air, is then discharged as vortex rings through an aperture opening.

7. The dosing principle and method according to any of claims 1 to 6, wherein the vortex transporting the medicament can, within the dosage, be changed in terms of size, velocity and volume.
- 5 8. An inhalation device for providing medicament for inhalation, including a vortex generator for generating a vortex entraining particles of medicament in a gas for inhalation by a user.
9. The inhalation device according to claim 8, further including a mouthpiece through
10 which a user in use inhales and the vortex generator is configured such that in use the vortex moves into the mouthpiece for inhalation by the user.
10. The inhalation device according to claim 8 or 9, wherein the vortex generator is a vortex ring generator.
- 15 11. The inhalation device according to any of claims 8 to 10, wherein the particles of medicament comprise powder.
12. The inhalation device according to any of claims 8 to 10, wherein the particles of
20 medicament comprise liquid droplets.
13. A method of providing medicament for inhalation, comprising the step of generating a vortex entraining particles of medicament in a gas for inhalation by a user.
- 25 14. The method according to claim 13, further comprising the step of directing the vortex into a mouthpiece through which a user inhales.
15. The method according to claim 13 or 14, wherein the vortex comprises a vortex ring.

16. The method according to any of claims 13 to 15, wherein the particles of medicament
comprise powder.

5 17. The method according to any of claims 13 to 15, wherein the particles of medicament
comprise liquid droplets.

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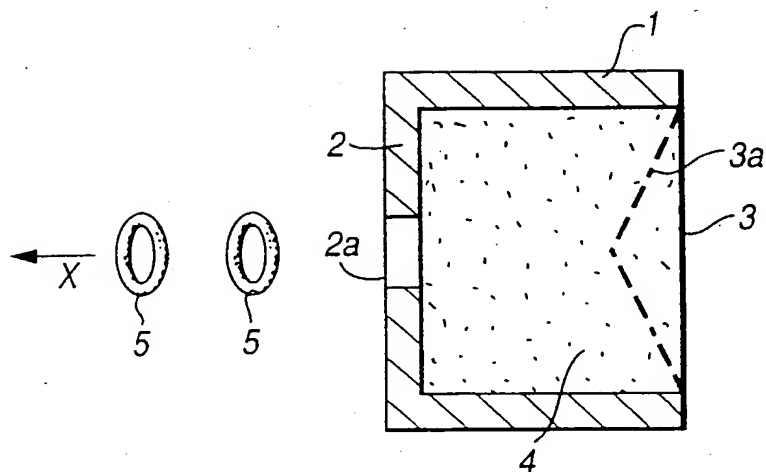


Fig. 1

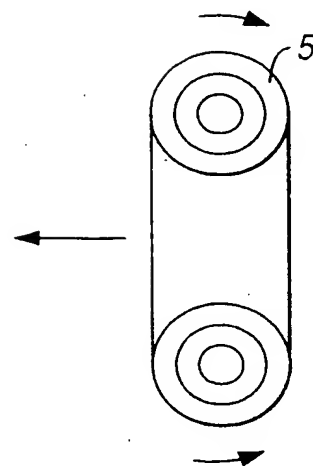


Fig. 2

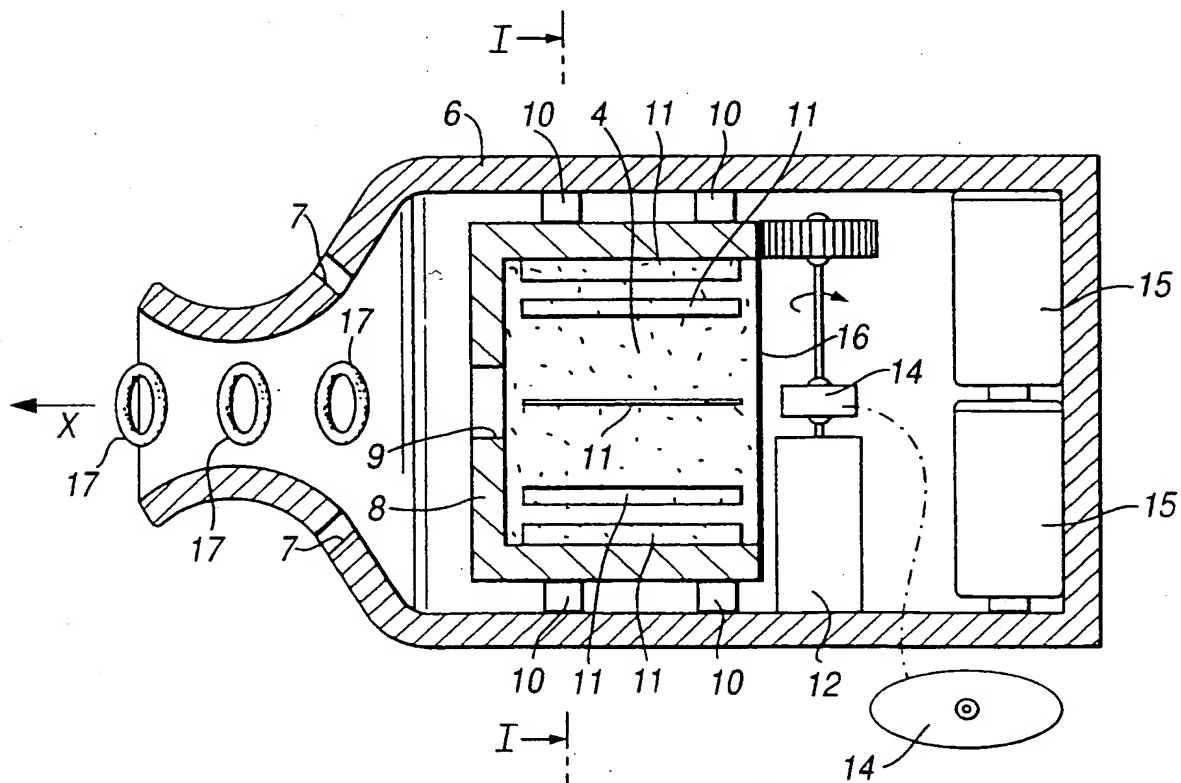


Fig. 3

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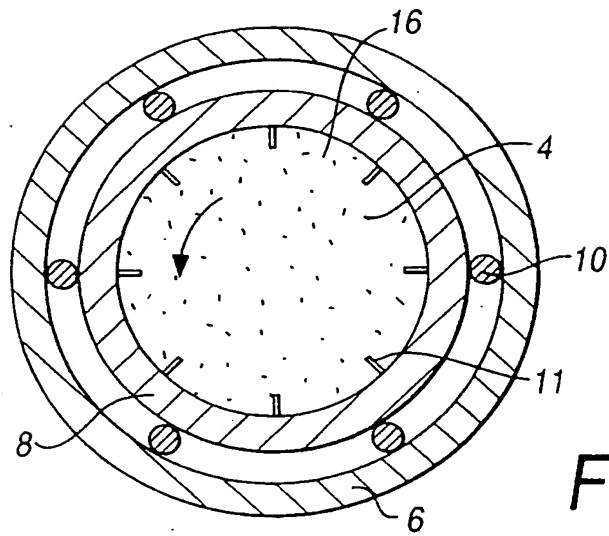


Fig. 4

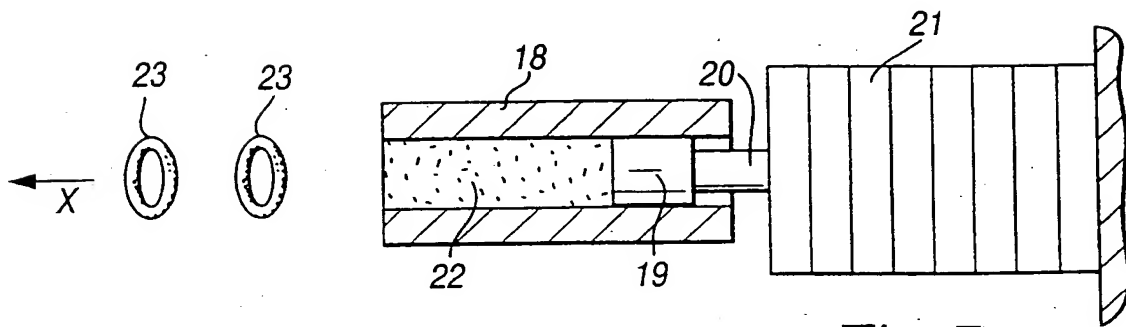


Fig. 5

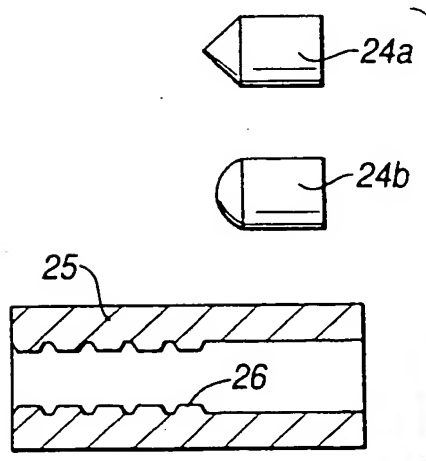


Fig. 6

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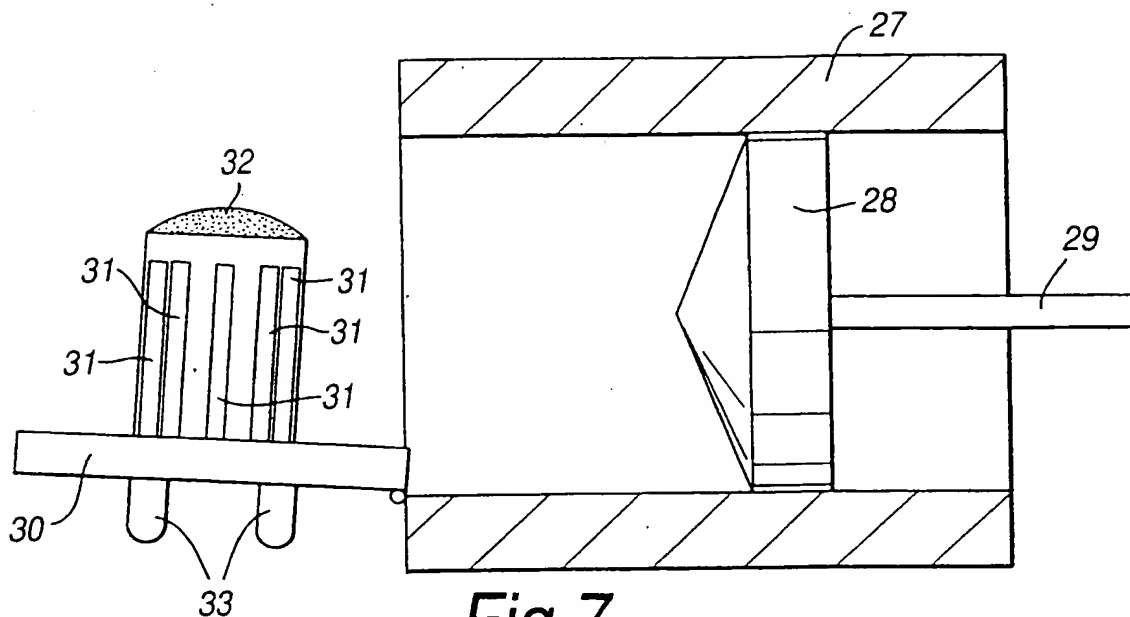


Fig. 7

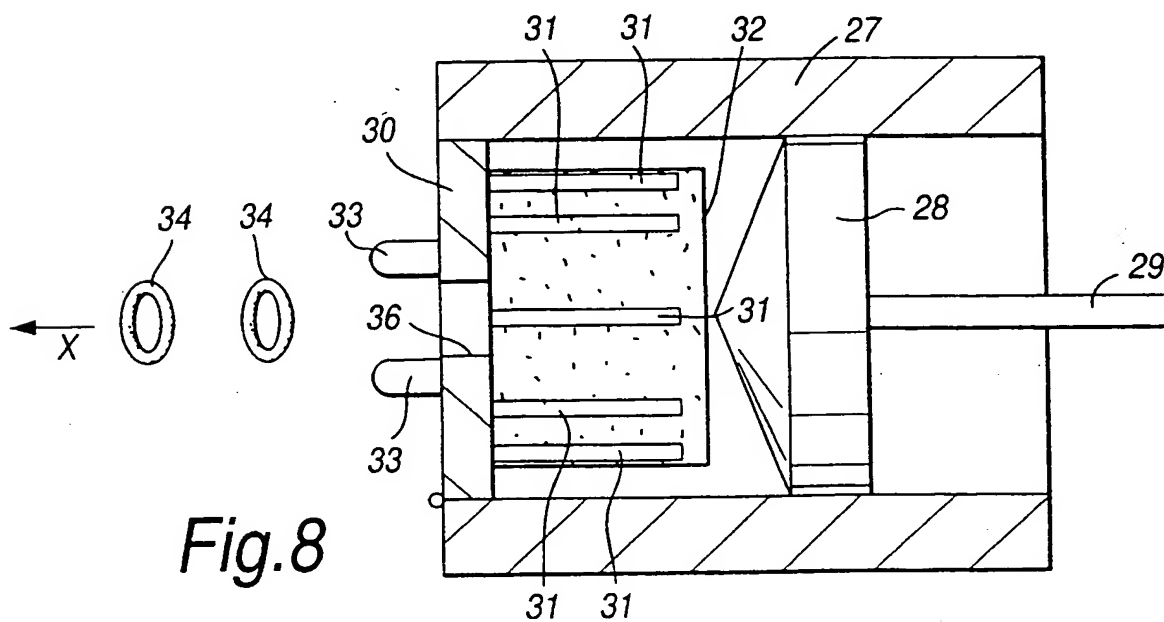


Fig. 8

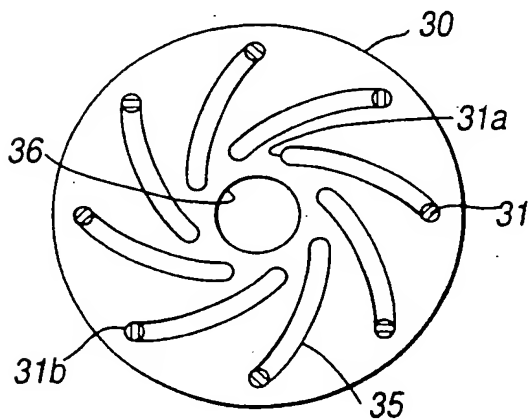


Fig. 9

INTERNATIONAL SEARCH REPORT

Internat Application No

PCT/Er 99/04160

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

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IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 483 953 A (COOPER GUY F) 16 January 1996 (1996-01-16) abstract column 11, line 17 - line 27; figures	1,3-5, 7-10, 12-15,17
X,P	US 5 823 434 A (COOPER GUY F) 20 October 1998 (1998-10-20) column 5, line 18 - line 33; figures	1,4,5, 8-17
A	US 4 090 320 A (LOIACONO CARMELO) 23 May 1978 (1978-05-23)	
A	US 2 788 607 A (WARD) 16 April 1957 (1957-04-16)	

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